

Remarks

Claims 116-119, 124-134 and 139-181 are presently pending in the subject application. Claims 131-144 and 153-174 were previously withdrawn as being directed to non-elected claim subject matter.

Reconsideration and allowance in view of the above amendments and the following remarks are respectfully requested.

Claims 120-123 and 135-138 are canceled herein without prejudice to the prosecution of the subject matter of these claims in this or a future continuing application.

Claim 116 has been amended herein to incorporate the limitations of prior dependent claim 120. Claim 175 has also been amended in a manner similar to claim 116.

Claims 176-181 are newly added herein. Claims 176, 178 and 180 depend from claims 116, 131 and 166, respectively, and recite that the base sequence of the target binding portion of the claimed probe is perfectly complementary to the base sequence of SEQ ID NO:3 or its complement. Claims 177, 179 and 181 depend from claims 116, 131 and 162, respectively, and recite that the base sequence of the claimed probe is perfectly complementary to the base sequence of SEQ ID NO:3 or its complement. The newly added claims are fully supported by the specification.

The claim interpretations in paragraph 5 of the Office Action appear to be solely for the Examiner's benefit in evaluating the patentability of the claims and, therefore, do not limit the scope of the claims.

Rejection Under 35 U.S.C. § 103

Claims 116-130, 145 and 175 stand rejected by the Examiner under 35 U.S.C. § 103(a) as being unpatentable over GenBank Accession No. NC_004718.1 in view of Peiris *et al.* (U.S. Publication No. 2005-0009009 A1). GenBank Accession No. NC_004718.1 is cited for disclosing the complete genomic sequence of the SARS coronavirus, and Peiris is cited for teaching the use of

oligonucleotides for a diagnostic assay for detecting SARS. Applicants respectfully traverse this rejection for the reasons that follow.

The probes of the claimed invention have been amended to recite a target binding portion that is perfectly complementary to all or a portion of a target sequence consisting of the base sequence of SEQ ID NO:3 or its complement (the “perfect complementarity” language contemplates DNA, RNA and chimeric probes, as well as analogs thereof). The target binding portion of the probes forms a hybrid stable for detection with the target sequence under stringent hybridization conditions, and the probes do not include other base sequences capable of stably hybridizing to nucleic acid derived from SARS-CoV under the recited conditions. Example 1 of the specification illustrates the unexpected benefits of the claimed probes, as probes having target binding portions that overlap with 3' and 5' end portions of SEQ ID NO:3 did appreciably hybridize to amplicon containing the complement of SEQ ID NO:3. *See* page 58, lines 1-9 of the specification (six base overlap with each of the probes represented by SEQ ID Nos. 44 and 45). The probes represented by SEQ ID Nos. 44 and 45 also had base overlaps with the probe represented by SEQ ID NO:46, which was used in Example 2 and exhibited specificity for the target sequence. Accordingly, Applicants submit that the claimed probes are fully patentable in view of the cited references.

Additionally, assays including amplification oligonucleotides of the claimed invention were demonstrated to have exquisite sensitivity, being 100% reactive at 80 copies/mL and nearly 90% reactive at both 25 and 50 copies/mL. *See* Table 2 in Example 2 at page 61 of the specification. Such results are not suggested by the amplification reactions of Peiris, which exhibited a sensitivity rate of between 31 and 81% on day 3 of disease onset, depending on sample size, RNA extraction protocol and method of amplification. *See* “Results” section of Peiris at numbered paragraphs 265-269 (*see* paragraph 269 and Figure 16 of Peiris for guidance on an expected range of copy numbers

on day 3 of disease onset). Thus, Applicants submit that the claimed amplification oligonucleotides are fully patentable in view of the cited references.

Claims 146-152 stand rejected by the Examiner under 35 U.S.C. § 103(a) as being unpatentable over GenBank Accession No. NC_004718.1 in view of Peiris *et al.* (U.S. Publication No. 2005-0009009 A1) and further in view of McDonough *et al.* (U.S. Patent No. 5,766,849). McDonough is cited for disclosing an amplification oligonucleotides having a promoter region recognized by a T7 RNA polymerase. Applicants submit that McDonough does not overcome the deficiencies of the other cited documents discussed above. Accordingly, withdrawal of this rejection is hereby respectfully requested.

Conclusion

Applicants submit that the subject application is in condition for allowance and early notice to the effect is hereby respectfully requested.

Response to Notice of Non-Compliant Amendment
and Substitute Reply Under 37 C.F.R. § 1.111
Date: August 17, 2007

Serial No. 10/825,757
Atty. Docket No. GP146-04.UT

Please charge any fees due in connection with this Reply, including the fee due for a three-month extension of time under 37 C.F.R. § 1.17(a)(3), to Deposit Account No. 07-0835 in the name of Gen-Probe Incorporated.

Respectfully submitted,

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